K002376

OCT 26 2000

Summary of Safety and Effectiveness

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

1. Submitter Information

Contact person:	William J. Pignato
Address:	Bayer Diagnostics Corporation 63 North Street Medfield, MA 02052 Phone: (508) 359-3825 FAX: (508) 359-3356 e-mail: william.pignato.b@bayer.com
Date Summary Prepared:	July 31, 2000

2. Device Information

Proprietary Name:	ADVIA: Centaur and ACS: 180 cPSA Assay
Common Name:	PSA Immunoassay
Classification Name:	Reclassified to Class II, classification numbers unknown

3. Predicate Device Information

Name:	Immuno cPSA Immunoassay
Manufacturer:	Bayer Diagnostics
510(k) Number:	P950021

4. Device Description

Prostate-specific antigen (PSA) is a single-chain glycoprotein normally found in the cytoplasm of the epithelial cells lining the acini and ducts of the prostate gland. PSA is a neutral serine protease of 240 amino acids involved in the lysis of seminal coagulum. PSA is present in the serum of males with normal, benign hyperplastic, and malignant prostate tissue. PSA exists predominantly in circulation in complexes with various protease inhibitors. The most prevalent form of complexed PSA (cPSA) that can be detected is bound to alpha-1-antichymotrypsin (ACT). cPSA can be useful for determining residual disease and early recurrence after therapy when used in conjunction with other diagnostic indices. cPSA levels increase in men with cancer of the prostate, and after radical prostatectomy cPSA levels routinely fall to the undetectable range. If prostatic tissue remains after surgery or metastasis has occurred, cPSA levels can be observed.

5. Statement of Intended Use

The Bayer Diagnostics complex PSA Immunoassay is intended for *in vitro* diagnostic use in the quantitative, serial determination of complexed prostate-specific antigen (cPSA) in human serum and to aid in the management of patients with prostate cancer using the ADVIA® Centaur™ and the ACS:180® Automated Chemiluminescence Systems.

6. Summary of Technological Characteristics

In the ADVIA Centaur cPSA assay, free PSA present in the sample is prevented from reacting with the total PSA antibodies by incubating the sample with a free-PSA-specific monoclonal mouse antibody (Pretreatment Reagent), which blocks the free PSA so that it is nonreactive in the ADVIA Centaur cPSA assay. The cPSA in the sample is then measured in the ADVIA Centaur cPSA assay. The ADVIA Centaur cPSA assay is a two-site sandwich immunoassay using direct chemiluminometric technology, which uses constant amounts of two antibodies. The first antibody, in the Lite Reagent, is a polyclonal goat anti-PSA antibody labeled with acridinium ester. The second antibody, in the Solid Phase, is a monoclonal mouse anti-PSA antibody, which is covalently coupled to paramagnetic particles.

A direct relationship exists between the amount of PSA present in the patient sample and the amount of relative light units (RLUs) detected by the system

7. Method Comparison

For 249 samples in the range of < 0.05 to 97.87 ng/mL (< 0.05 to 97.87 µg/L), the relationship between the ACS:180 cPSA assay and an alternate method is described by the equation:

ACS:180 cPSA = 0.93 (Immuno 1® cPSA) + 0.02 ng/mL

Correlation coefficient (r) = 0.996

The device, which is scheduled to be placed into commercial distribution, is substantially equivalent to the Immuno 1 cPSA assay Immunoassay also manufactured by Bayer Diagnostics Corporation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 26 2000

Mr. William J. Pignato
Director or Regulatory Affairs
Bayer Corporation
63 North Street
Medfield, Massachusetts 02052-1688

Re: K002376
Trade Name: Bayer ACS: 180/ADVIA Centaur Complex PSA Immunoassay
Regulatory Class: II
Product Code: LTJ
Dated: August 2, 2000
Received: August 4, 2000

Dear Mr. Pignato:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K002376

Device Name: Bayer Diagnostics ACS:180 and ADVIA Centaur PSA Assay

Indications for Use:

The Bayer Diagnostics complex PSA Immunoassay is for the quantitative determination of prostate specific antigen in serum to aid in the management of cancer patients in whom changing concentrations of PSA are observed using the Bayer Diagnostics ASC: 180 and ADVIA Automated Chemiluminescence Systems.

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Maker

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002376

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)